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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,319	10/18/2005	Mira Susa Spring	PA/4-32899A	2731

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	
MAIL DATE	DELIVERY MODE
05/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,319	SUSA SPRING ET AL.	
	Examiner	Art Unit	
	CELINE X. QIAN	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-51 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 12, 14-20 and 46-51, drawn to a method of screening for an agent that modulates the differentiation into osteoblasts, comprising a) preparing a first gene or gene family expression profile of a cell population comprising MC3T3-E1 or MC3T3-1B cells and/or assaying an activity of a protein encoded by at least one gene or a member of gene family member of Table 1; b) exposing said cell population to the agent, c) preparing second gene or gene family expression profile of the agent exposed cell population and or assaying an activity of a protein encoded by at least one gene or a member of a gene family of Table 1 of the exposed cell population; and d) comparing the first and second expression profile or first and second activity to an expression profile and or activity of an osteoblast differentiated MC3T3-E1 or MC3T3-1b cell population.

Group II, claim(s) 6, 8 and 10, drawn to a method of diagnosing a condition characterized by abnormal deposition of bone tissue/abnormal rate of formation of osteoblasts/osteoporosis, comprising detecting the level of expression of and/or activity of a protein encoded by at least one gene or member of a gene family of Table 1, wherein differential expression or activity of the gene or member of a gene family is indicative of abnormal bone tissue deposition/abnormal rate of formation of osteoblasts/osteoporosis.

Group III, claims 7, 9 and 11, drawn to a method of monitoring the treatment of a patient with a condition characterized by abnormal bone tissue formation/abnormal rate of formation of osteoblasts/osteoporosis, comprising a) administering a pharmaceutical composition to the patient; b) preparing a gene expression profile and/or assaying an activity of a protein encoded by at least one gene or a member of gene family member of Table 1 in a cell or a tissue sample from the patient; c) comparing the expression profile or the activity to an expression profile and or activity from a MC3T3-E1 or MC3T3-1b cell population or an osteoblast differentiated MC3T3-E1 or MC3T3-1b cell population.

Group IV, claim 13, drawn to a method of monitoring the progression of bone tissue deposition in a patient; comprising a) detecting the expression and or activity level of one

or more genes or members of a gene family of Table 1, wherein differential expression and /or activity is indicative of bone tissue deposition.

Group V, claims 21-34, drawn to a composition comprising at least two oligonucleotides, wherein each of the oligonucleotides comprises a sequence that specifically hybridizes to a gene or member of a gene family of Table 1, wherein the composition further comprises a solid support.

Group VI, claims 35-40, drawn to a computer system comprising a) a database containing information identifying the expression and/or activity level in osteoblasts of a set of genes comprising one or more genes or members of a gene family in Table 1; and b) a user interface to view the information.

Group VII, claims 41-45, drawn to a method of using a computer system of group VI to identify the expression level in a tissue or cell of a set of genes comprising at least two of the genes or members of gene families in Table 1 comprising: comparing the expression level of at least one gene or member of a gene family in Table 1 in the tissue to the level of expression of gene in the database.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group I is comparing the expression profile of a gene or gene family comprising a cell population comprising MC3T3-E1 cells or the protein activity of a protein encoded by a gene or gene family member of Table 1 in said cells before and after the cells exposed to a differentiation agent in osteoblast, which is shown by Kitching et al., (see IDS, Bone and Mineral Metabolism, 2002, Vol. 20, pages 269-280) to lack novelty or inventive step over the disclosed method of comparing the expression of genes in MC3T3-E1 cells. Claim recites comparing the profile of at least one gene or a member of gene family from Table 1, including Procollagen, type I, alpha 1 and Fibulin 2, which is present in Table 3 of Kitching et al. Therefore, the special technical feature of Group I and does not make a

contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

Additionally, each group named above is subject to further restriction. Each group detailed above reads on compositions or methods that comprise different gene(s) or combination of gene(s). Each gene, or combination of genes, does not share a special technical feature under the PCT Rule 13.2 because they are unrelated sequences, and the compositions and methods that comprise the gene or combination of genes cannot be considered to form a single general inventive concept under PCT Rule 13.1, and a further restriction is applied to each group. Applicant must further elect a single gene or a specific combination of genes. Applicant is further required to distinctly point out the location in the drawings, figures, Tables or SEQ IDs of the instant application to which the elected gene is drawn. Please include in the election of sequence or specific combination of sequence the SEQ ID(s), the genebank numbers(s) (or any other identifier), the table or figure number, and the row or column location in the table. This is NOT an election of species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636